

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 50-R-0001
CUSTOMER NUMBER: 41

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

E I Dupont Denemours & Company Inc
Haskell Laboratory
Elkton Road
P.O. Box 50
Newark, DE 19714

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquillizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reaso such drugs were not used must be attached to this report | F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E) |
|---|--|--|---|---|--|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | 13 | 333 | 11 | 43 | 387 |
| 9. Non-human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| | | | | | |
| 13. Other Animals | | | | | |
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ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquillizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary Inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(B)(6) (B)(7)(c)

DATE SIGNED

14 Nov 2008



DuPont Haskell Global Centers
for Health & Environmental Sciences
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

November 20, 2008

Elizabeth Goldentyer, DVM
USDA, APHIS, REAC
Eastern Regional Office
920 Main Campus Drive
Raleigh, NC 27606

RE: ANNUAL REPORT, CUSTOMER NO: 41, CERTIFICATE NO: 50-R-0001

Dear Dr. Goldentyer:

In accordance with the Animal Welfare Act (AWA) regulations, DuPont Haskell Global Centers for Health and Environmental Sciences is filing its Annual Research Facility Report (APHIS Form 7023) documenting animal usage for the Federal Fiscal Year 2008 (October 1, 2007 through September 30, 2008).

(b)(4)

Three (3) rabbits used in (b)(4) met the criteria described on APHIS Form 7023 Column "E". These studies comply with test guidelines (b)(4)

(b)(4)

(b)(4)

in Rabbits – the purpose of this study is to provide DuPont with a safety assessment and /or information for registration of the product.

(b)(4)

Five (5) rabbits used in (b)(4) met the criteria described on the APHIS Form 7023 Column "E". These studies comply with test guidelines (b)(4)

(b)(4)

Ten (10) rabbits used in (b)(4) met the criteria described on the APHIS Form 7023 Column "E". Although these screens do not comply with any test guidelines, they use fewer animals than guideline studies.

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(b)(4) – the purpose is to provide DuPont with a safety assessment and/or information for registration of the product. Test guidelines for these study types do not allow for the use of anesthetics, analgesics, or tranquilizing drugs, other than allowing use of local anesthetics in (b)(4) where extreme pain is expected. Animals experiencing extreme pain are euthanized immediately. Most tested substances are novel materials. Exceptions must be approved by the IACUC. (b)(4) (b)(4) are not conducted for test substances if it is expected they will produce corrosion or severe irritation, based on measured pH or the results of an *in vitro* assay (i.e., Corrositex). Haskell follows the principles of the 3Rs in all of our work.

(b)(4)

Twenty-five (25) rabbits used in (b)(4) met the criteria described on APHIS Form 7023 Column “E”.

(b)(4)

Regulatory agency guidelines related to this type of testing include:

- U.S. EPA: Health Effects Guidelines Office of Prevention, Pesticides, and Toxic Substance (b)(4)
- Organization for Economic Cooperation and Development (OECD/OCDE), (b)(4)
- International Conference on Harmonization (ICH); Tripartite Guidelines on Detecting of Toxicity to Reproduction for Medicinal Products, (b)(4)

The IACUC approved conducting (b)(4) listed above without the use of anesthetics, analgesics or tranquilizing drugs. These studies are designed to evaluate the safety of test substances: co-administration of drugs intended to manage pain and distress in surviving animals could potentially interfere with the objective of the test and invalidate the results of the study. In practice, it is our goal that these study animals do not experience prolonged unmitigated pain or distress. Death is not an endpoint of these studies. Animals potentially experiencing prolonged pain or distress are euthanized immediately. This includes animals with continued significant weight loss or decreased food consumption, but no other clinical signs of pain or distress.

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Haskell's IACUC has not approved any exceptions to the AWA standards during the previous year for any USDA covered species.

If you have any questions or require clarification, please do not hesitate to contact me.

(B)(6) (B)(7)(c)



DuPont Haskell Global Centers
for Health & Environmental Sciences
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

FEB 7 4 2009

February 20, 2009

Nicolette Petervary, VMD
Regional Animal Care Specialist
Eastern Regional Office
920 Main Campus Drive
Raleigh, NC 27606

RE: ADDENDUM TO ANNUAL REPORT FOR FY 2008, CUSTOMER NO: 41,
CERTIFICATE NO: 50-R-0001

Dear Dr. Petervary:

This letter is an addendum to DuPont Haskell's annual report for FY 2008, provided in response to your February 5, 2009 request for clarification of 10 rabbits reported on the APHIS form 7023 in column E, and described as used in screens not complying with any guidelines.

These 10 rabbits were used in (b)(4) Any animal with severe irritancy was euthanized prior to completion of the study in order to avoid unnecessary pain and distress. However, anesthetics and analgesics were not used because of potential interference with test results

(b)(4)

(b)(4)

All procedures and methodology on the screening tests actually followed test guidelines (b)(4) with the only exception that fewer animals are used. The IACUC approved this screening work which is predictive of the results of the guideline-compliant studies.

If you have any questions or require clarification, please do not hesitate to contact me.

(B)(6) (B)(7)(c)

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